

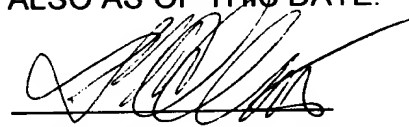



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CASE 1161

PATENT

I CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL SUFFICIENT POSTAGE ATTACHED IN AN ENVELOPE ADDRESSED TO THE COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON D.C. 20231 ON MARCH 11, 2002 AND THAT MY SIGNATURE IS ALSO AS OF THIS DATE.


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71 A.P.E.
4-18


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Joseph E. Coury, et al.

Serial No. 09/691,713

Filed: October 18, 2000

Examiner: Patel, Mital

Art Unit 3761

Paper

Title: Personal Gas Supply Delivery System

Amendment A

Dear Sir:

In response to the Official Action of November 9, 2001 please enter this amendment.

Please amend the specification as follows:

Amend the specification at page 14, line 9 to insert after the word 'transmits', --a **radio signal**--.

Amend the specification at page 10, line 16 to insert, -- arrow--, for "double-headed arrows".

Amend the specification at page 12, line 14 to delete, "98" and insert therefore, --90--.

Amend the specification at page 12, line 15 to delete, "98" and insert therefore, --90--.

Amend the specification at page 12, line 16 to delete, "98" and insert therefore, --90--.

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Amend the specification at page 12, line 18 to delete, "**98**" and insert therefore, **--90--**.

Amend the specification at page 12, line 20 to delete, "**98**" and insert therefore, **--90--**.

Amend the specification at page 14, line 12 to delete, "**vessel**", and insert therefore, **--device--**.

Amend the specification at page 14, line 14 to insert before the number '222', insert **--(or moisturizing vessel) --**.

Amend the specification at page 15, line 6 to insert, **-- arrow--**, for "double-headed arrows".

Amend the specification at page 15, line 15 to delete, the first instance of "**a reset switch 306**", and insert therefore, **--an on off switch 310--**.

Amend the specification at page 15, line 15 to delete the second instance of, "**reset switch 306**", and insert therefore, **--on off switch 310--**.

Amend the specification at page 15, line 22 to delete, "**Accordingly, the gas flow alarm 20 may also provide an on off switch (or a test feature) 310.**"

Amend the specification at page 12, lines 22 through line 25, to delete, "A retaining strap (not shown) is conveniently connected with the nasal cannula tube 98. The retaining strap 118 permits the gas distributive device 70 to be retained around the neck of the patient while the patient is receiving the medical gas."

Please amend the claims as follows:

Claim 2 Once Amended. The personal gas supply delivery system according to claim 1 wherein said second conduit is further connected with a gas distributive device, said gas distributive device for receiving the effluent gas and distributing the effluent gas to a subject desiring to receive the effluent gas wherein the gas distributive device includes a nasal cannula.

Claim 12 Once Amended. The personal gas supply delivery system according to claim 11 wherein said second conduit is further connected with a gas distributive

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device, said gas distributive device for receiving the effluent gas and distributing the effluent gas to a subject desiring to receive the effluent gas wherein the gas distributive device includes a nasal cannula.

Claim 20 Once Amended. The personal gas supply delivery system according to claim [7] 19 wherein the second person is alerted by [a radio signal] the receiver.

Claim 21. Once Amended. A personal gas supply delivery alarm system comprising: _____

a first conduit, for when in use receiving a supply of a gas at a first pressure

from a first gas supply line,

said first conduit connected with a gas flow alarm, said gas flow alarm for when in use

for determining an instantaneous difference in the pressure or volume of the gas per unit of time and the volume of the [effluent] gas per unit of time,

a second conduit connected with said gas flow alarm, for when in use receiving the supply of gas through said gas flow alarm,

said first conduit having a first connector, for when in use providing a detachable

airtight seal with a compatible connector on the gas supply line,

said first connector located distally from said gas flow alarm, and

said second conduit having a second connector, for when in use providing a detachable airtight seal with a compatible connector on a second gas supply line, said second connector located distally from said gas flow alarm,

said second gas supply line terminating in a nasal cannula.

Cancel Claim 22 without prejudice.

Claim 23. Once Amended The personal gas supply delivery system according to claim 21 wherein the gas flow alarm is set to alert a subject desiring to receive the gas

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when an instantaneous difference in the volume of the **[influent]** gas per unit of time **[and the volume of the effluent gas per unit of time has met at least one predetermined setting]** .

Claim 25. Once Amended The personal gas supply delivery system according to claim 21 wherein the gas flow alarm is set to alert **[the] a** recipient of the gas by at least one of an audible signal, a visual signal, and a vibratory signal.

Claim 26. Once Amended The personal gas supply delivery system according to claim 21 wherein the gas flow alarm is set to alert a subject desiring to receive the **[effluent]** gas when the volume of the gas or the pressure of the gas has met at least one predetermined setting.

Claim 29. (Once Amended Formerly 30). The personal gas supply delivery system according to claim **[29] 28** wherein the gas flow alarm has an anterior surface including an alarm reset or test feature located substantially flush with said anterior surface.

Formal Matters

The Examiner in paragraph 1 Official Action has noted that several reference characters were not included in the drawings. The applicant submits a second set of drawings and also a red lined version of the second set of drawings.

The Examiner in paragraph 2 of the Official Action has noted that informal drawings were submitted with the application and that some of the figures were not clear. As formal drawings have been submitted is believed that the objection made in paragraph 2 is moot.

The Examiner in paragraph 3 of the Official Action has stated that reference character "306" has been used to designate both the test switch and the reset switch. The applicant has corrected the drawings such that "306" refers only to the test switch and new reference character 310 designates the on off switch.

The Examiner in paragraph 4 of the Official Action has noted that reference characters in 220 and 222 points to the same structural element. The reference

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character 220 designates the overall device shown. Reference character 222 designates the vessel.

The Examiner in paragraph 5 of the Official Action states that there is a lack of antecedent basis in the specification for the claimed terminology "moisturizing vessel" and "radio signal". Antecedent basis has been supplied as shown above.

At paragraph 6 of the Official Action the Examiner has noted that claim 27 was omitted and thus original claims 28 through 30 inclusive have been renumbered 27 through 29 inclusive.

Discussion of the 35 USC 112 Rejections

The Examiner has stated in paragraph 8 of the Official Action that claim 20 lacks antecedent basis for the term "the second person". The Examiner further states that claim 21 lacks antecedent basis for the term "the effluent gas". The Examiner also states that claim 23 lacks antecedent basis for the term "the influent gas". The Examiner further states that claim 25 lacks antecedent basis the term "the recipient". Lastly, the Examiner states that claim 26 lacks antecedent basis for the term "the effluent gas".

Each of the rejections stated in paragraph 8 have been dealt with by amendment. Therefore the rejection made under 35 USC 112 is now moot.

Claims 1 through 21 inclusive and claims 23 through 29 inclusive are pending and reconsideration is requested.

Discussion of the 35 USC 102 Rejections

The Examiner has rejected claims 1, 3, 4, 5, 6, 7, 11, 13, 14, 15, 17, 21, 23, 24, 25, 26, and 29 (renumbered 28) based on Bird United States Patent 5,165,398 (hereinafter the Bird patent).

Prior to discussing the nature of the rejections the applicant feels that a brief review of the claimed invention will be the Examiner in determining the differences between that which is claimed and the cited art.

The present invention deals with an uncomplicated system for providing a gas such as oxygen to a person in need of such gas. A difficulty which is been found with such oxygen delivery systems, particularly those which are portable or located in the home of the user, is reliability. Portable oxygen generation systems use a thin hose to deliver the oxygen from a tank or oxygen separator to the user. The hose may become crimped or cut at any point thus depriving the user of needed oxygen who may be of diminished capacity to determine if the oxygen is being delivered.

Further, as the oxygen supply to a user needs moisture to prevent over drying of the user's airways it is desirable to moisturize the oxygen. The oxygen which is moisturized is typically accomplished with a vessel containing water through which the oxygen is bubbled. The moist oxygen is then supplied to the user through another thin hose, and in the case of present invention, the thin hose is connected with nasal cannula.

The use of a vessel presents a significant possibility for the loss of the entire supply of oxygen. Typically, a bottle used to moisturize the oxygen will be a plastic screw top bottle and the top the bottle from which the oxygen is received and moisturized oxygen dispensed will also be plastic. A significant potential exists for the bottle to be damaged at the threads through repeated usage. Another factor in the use of the bottle is where the screws in the cap are not aligned properly with the threads in the bottle thus providing direct leakage of the oxygen in which case the user does not receive the oxygen. As previously noted, the user of the oxygen may be of diminished capacity and will not know that the flow of oxygen is interrupted.

The present invention provides an alarm in direct proximity to the user of the oxygen. The alarm is typically portable or generates a light to permit the user or another in the vicinity to be alerted to the lack of oxygen flow. The alarm system of invention provides a reliable system for a user of oxygen in a portable or home setting, or for that matter in a hospital, to know on a reliable basis that the oxygen is being supplied to the user.

The gas flow described in the Bird patent is as follows:

The oxygen blender 29 is supplied with oxygen and air in a conventional manner. Thus as shown, the blender is provided with an oxygen inlet fitting 31 which is connected to a tube 32 that is connected to a source of oxygen. Similarly, the blender 29 is provided with an air inlet fitting 33 that is connected by a tube 34 to a suitable source of air. The oxygen blender is provided with a control knob 36 by which the ratio of oxygen to air can be varied from 21% to 100%. A flow meter 37 of a conventional type is mounted on the oxygen blender 29 and measures the flow of the mixture of oxygen air passing through the outlet 28.

An oscillator canister 41 is provided that is mounted on the outlet of pneumatic clutching means 42 (PHASITRON) which is mounted within the case 22 and has its outlet 47 extending through the top wall 26 of the case 22. Bird patent Column 3, lines 33 et seq.

The Bird patent continues:

Referring to the breathing circuit shown in FIG. 3, percussion gas supplied from the oscillator canister 41 is delivered at a pulse rate which can vary from 0 to 1500 cycles per minute and typically approximately 900 cycles per minute to the swivel tee 166 and into the patient adapter 167 which takes the form of the endotracheal tube. These percussion gases are superimposed upon a continuous supply of gas which is delivered through a PHASITRON 177 that serves as a failsafe distribution manifold into the heated humidifier 182. The humidifier wets the gas supplied to the humidifier 182 and delivers the same to the inspiratory circulation tubing 183 where it is delivered to the swivel tee 166. The gases are also supplied to the expiratory circulation tubing 189 and to the PHASITRON 191. In this way, the entire breathing circuit is pressurized and causes gases to flow into the lungs of the patient through the endotracheal tube 167. Thus when the inlet tube 192 of the PHASITRON 191 is pressurized, gases will be supplied to the patient and when the inlet 192 is depressurized, the continuous flow of gas will flow out of the exhalation port 194. In this way, the PHASITRON 191 serves as a

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pneumatic clutch for controlling the flow of gas into the lungs of the patient. If the demand CPAP regulator 262 is in operation, this will supply gas under pressure to the tubing 192 which causes closure of the PHASITRON 191.

Assuming a constant inflow of 20 liters per minute through the inspiratory circulation tubing 183 and by regulating the outflow from the PHASITRON 191, the patient must breath against a constant positive airway pressure as determined by the demand CPAP regulator. Bird patent Column 10, lines 45 et seq.

In contrast the flow of gas in the present invention is from the hollow flexible tubing 14 through the gas flow alarm 20 and to the user through nasal fittings 102 and 104.

The Examiner has rejected claim 1 based on the Bird patent as lacking novelty. The Examiner is correct insofar as it the Bird patent teaches a moisturizing vessel 182 and a gas alarm 287.

However, a difference between the Bird patent and claim 1 of the present invention is that the gas alarm 287 of the Bird patent is located upstream with reference to oxygen flow from the moisturizing vessel 182. That is, the gas alarm recited in claim 1 is downstream from the applicant's moisturizing vessel. Claim 1 also recites measures the instantaneous pressure differential of the influent gas and the effluent gas.

Therefore, claim 1 is novel over the Bird patent. Thus, the rejections based on the Bird patent regarding claim 1 and all claims dependent from claim 1 should be removed.

The applicant has without regard to the Bird patent amended claim 2 to recite that the gas distributive device is a nasal cannula. The Bird patent, at column 6, line 8 teaches an endotracheal tube not nasal cannula.

The applicant cannot locate in the Bird patent a teaching that a gas flow alarm is set to alert a subject receiving the effluent gas. Therefore, it is believed that claim 4 is

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novel over the Bird patent. Thus, the rejection to claim 4 over the Bird patent should be removed and such as requested.

The applicant's claim 5 requires, in part, that the subject is alerted to a gas flow problems by a visible light. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 5 over the Bird patent should be removed and such as requested.

The applicant's claim 6 requires, in part, that the subject is alerted to a gas flow problems audibly. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 6 over the Bird patent should be removed and such as requested.

The applicant's claim 8 states that a gas flow alarm has located on an anterior surface an on off switch which is substantially flush with or below the anterior surface of the gas alarm. The purpose of the applicant's invention in claim 8 is because the proximal location of the gas alarm to the receiver of the gas. If the alarm on off switch feature is not located as described in claim 8 then the recipient of the gas would be more likely to accidentally disable the alarm system.

There is no disclosure in the Bird patent, nor is there any need given the device described in the Bird patent, to position the on off switch in claim 8. Thus, the rejection to claim 8 over the Bird patent should be removed and such as requested.

The applicant's claim 9 states that a second person is alerted to an interruption in gas flow by a transmitter and receiver. As the recipient of the gas is the first person and the Bird patent does not disclose alerting a first person it is not possible to alert a second person. Moreover, the Bird patent does not teach the use of a transmitter and/or receiver. Thus, the rejection to claim 9 over the Bird patent should be removed and such as requested.

Similar to claim 9 is claim 10 which states that a second person is alerted by a radio signal. As the Bird patent does not teach the use of a transmitter and/or receiver

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it cannot teach alerting by a radio signal. Thus, the rejection to claim 10 over the Bird patent should be removed and such as requested.

The Examiner has rejected claim 11 based on the Bird patent as lacking novelty.

However, a difference between the Bird patent and the claim 11 of the present invention is that the Bird patent locates the gas alarm 287 upstream with reference to oxygen flow from the moisturizing vessel 182. That is, the gas alarm recited in claim 1 is downstream from the applicant's moisturizing vessel. Claim 11 also recites measuring the instantaneous volume differential of the influent gas and the effluent gas.

Therefore, claim 11 is novel over the Bird patent. Thus, the rejections based on the Bird patent regarding claim 11 and all claims dependent from claim 1 should be removed.

Claim 12 is similarly novel over the Bird patent. The applicant has without regard to the Bird patent amended claim 12 to recite that the gas distributive device is a nasal cannula. The Bird patent, at column 6, line 8 teaches an endotracheal tube not nasal cannula.

The applicant cannot locate in the Bird patent any teaching that the gas flow alarm is set to alert a subject receiving the effluent gas. Therefore, it is believed that claim 14 is novel over the Bird patent. Thus, the rejection to claim 14 over the Bird patent should be removed and such as requested.

The applicant's claim 15 requires, in part, that the subject is alerted to a gas flow problems by a visible light. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 15 over the Bird patent should be removed and such as requested.

The applicant's claim 16 requires, in part, that the subject is alerted to a gas flow problems audibly. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 16 over the Bird patent should be removed and such as requested.

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The applicant's claim 18 states that a gas flow alarm has located on an anterior surface an on off feature which is substantially flush with or below the anterior surface of the gas alarm. The purpose of the applicant's claim 18 is because the proximal location of the gas alarm to the receiver of the gas. If the on off feature is not located as described in claim 18 then the recipient of the gas would be more likely to accidentally disable the alarm system. There is no disclosure in the Bird patent, nor is there any need given the device described in the Bird patent, to position the alarm on off switch in claim 18. Thus, the rejection to claim 18 over the Bird patent should be removed and such as requested.

The applicant's claim 19 states that a second person is alerted to an interruption in gas flow by a transmitter and receiver. As the recipient of the gas is the first person and the Bird patent does not disclose alerting the recipient of the gas it is not possible to alert a second person. Moreover, the Bird patent does not teach the use of a transmitter and/or receiver. Thus, the rejection to claim 19 over the Bird patent should be removed and such as requested.

Similar to claim 19 is claim 20 which states that a second person is alerted by a radio signal. As the Bird patent does not teach the use of a transmitter and/or receiver it cannot teach alerting by a radio signal. Thus, the rejection to claim 20 over the Bird patent should be removed and such as requested.

Claim 21 recites a device similar to that recited in claims 1 and 11 wherein said second gas supply line terminates in a nasal cannula. The Bird patent teaches a device wherein intubation is required. Thus, claim 21 is novel over the Bird patent and the rejection should be removed.

Regarding Claim 23 the applicant cannot locate in the Bird patent any teaching that the gas flow alarm is set to alert a subject receiving the gas. Therefore, it is believed that claim 23 is novel over the Bird patent. Thus, the rejection to claim 23 over the Bird patent should be removed and such as requested.

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The applicant's claim 25 requires, in part, that the subject is alerted to a gas flow problems by a visible light. As previously stated, nothing in the Bird patent teaches alerting the subject receiving the gas by any means. Thus, the rejection to claim 25 over the Bird patent should be removed and such as requested.

The applicant's claim 27 (renumbered from 28) states that a second person is alerted to an interruption in gas flow by a transmitter and receiver. As the recipient of the gas is the first person and the Bird patent does not disclose alerting the recipient of the gas is not possible to alert a second person. Moreover, the Bird patent does not teach the use of a transmitter and/or receiver. Thus, the rejection to claim 27 over the Bird patent should be removed and such as requested.

The applicant's claim 29 (renumbered from 30) states that a gas flow alarm has located on an anterior surface an alarm reset or test feature which is substantially flush with or below the anterior surface of the gas alarm. The purpose of the applicant's claim 29 is because the proximal location of the gas alarm to the receiver of the gas. If the alarm reset or test feature is not located as described in claim 8 then the recipient of the gas would be more likely to accidentally disable the alarm system. There is no disclosure in the Bird patent, nor is there any need given the device described in the Bird patent, to position the alarm reset or test feature in claim 29. Thus, the rejection to claim 29 over the Bird patent should be removed and such as requested.

Discussion of the 35 USC 103 Rejections

The Examiner has rejected claims 2, 8, 9, 10, 12, 18, 19, 20, 22, 28 (renumbered 27), and claim 29 (renumbered 28) based on Bird patent.

The Examiner has chosen to address claims 2, 12, and 22 together. Claim 22 has been cancelled without prejudice. As to claims 2 and 12 the Examiner merely states that gas distributive devices are known. However, within the context of the claims and the Bird patent there is no motivation to provide the gas distributive device as recited in dependent claim 2 (depending from claim 1) and claim 12 (depending from claim 11). Thus, the rejection of claims 2 and 12 should be removed.

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The Examiner has also addressed claims 8, 18, and 30 (renumbered 29) together. The Examiner states that there is no recited advantage over the Bird patent regarding claims 8, 18, and 30 (renumbered 29). There is no requirement in United States patent law for an advantage over the cited art. The Examiner must provide reasoning as to why one skilled in the art would change the reference teachings to obtain the claimed invention.

The purpose of the applicant's claims 8, 18, and 30 (renumbered 29) is because the proximal location of the gas alarm to the receiver of the gas. If the alarm on off feature is not located as described in claims 8, 18, and 30 (renumbered 29) then the recipient of the gas would be more likely to accidentally disable the alarm system. Thus, the rejection of claims 8, 18, and 30 (renumbered 29) should be removed.

The rejection of claims 9, 10, 19, 20 and 22 are treated together by the Examiner relating to the use of a transmitter and receiver. The applicant cannot discuss this rejection as the Examiner has proved no reasoning as to why one skilled in the art would select the parameters of these dependent claims for inclusion in the respective independent claims and why such would be obvious from the Bird patent.

Claims 1 through 21 inclusive and claims 23 through 29 inclusive are pending and reconsideration is requested, and removal, of the rejections made in the present Official Action. Should questions concerning this application arise the Examiner is urged to telephone the undersigned to advance prosecution of this application. The applicant believes the application is in condition for allowance and such is earnestly solicited.

Respectfully submitted,


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